2/11/99

K983702

Roche

510(k) Summary

Abuscreen ONLINE® Benzodiazepines

In accordance with the Safe Medical Devices Act of 1990, a 510(k) summary is provided as outlined in 21 CFR 807.92.

The assigned 510(k) number is: K983702

I. Identification of 510(k) Sponsor:

Roche Diagnostic Systems, Inc.
a subsidiary of Hoffmann-La Roche, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

510(k) Submission dated October 20, 1998

Contact: Rita Smith
Senior Regulatory Affairs Associate
Phone: (908) 253-7545
Fax: (908) 253-7547

II. Device Name:

The device name, including both the trade/proprietary name and the classification name are provided in the table below.

Table 1

Product Name	Classification Name	Product Code	CFR Number and Regulatory Class
Abuscreen ONLINE for Benzodiazepines	Enzyme Immunoassay, Benzodiazepine	JXM	862.3170 Class II

III. Identification of the legally marketed device to which the 510(k) sponsor claims equivalence:

The following table identifies the legally marketed devices to which Roche Diagnostic Systems, Inc. claims equivalence.

Table 2

Product Name	Predicate Product Name	510(k) Number and Date Predicate Cleared
Abuscreen ONLINE for Benzodiazepines	Abuscreen ONLINE for Benzodiazepines	K914509 11/1/91

IV. Description of the Device/Statement of Intended Use:

Abuscreen ONLINE Benzodiazepines is an *in vitro* diagnostic test for the qualitative and semiquantitative detection of benzodiazepines in human urine on automated clinical chemistry analyzers at cutoff concentrations of 100 ng/mL, 200 ng/mL, and 300 ng/mL. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Measurements obtained by this device are used in the diagnosis of benzodiazepine use or abuse.

The proposed Abuscreen ONLINE Benzodiazepines test kit is specifically intended for use on the Hitachi 917 Analyzer and future similar analyzer models. It was adapted from the currently marketed Abuscreen ONLINE Benzodiazepines test kit. The labeling and packaging have been changed for use on the Hitachi 917 Analyzer as well as an addition of a surfactant to the diluent. This modified test kit is not a replacement to the currently marketed kit.

The Hitachi 917 Analyzer System is a fully automatic, computer-controlled system for clinical chemistry. It was conceived for both quantitative and qualitative *in vitro* determination using a large variety of tests for analysis, e.g. in serum and urine. Integrated in the system is an ion-selective unit for determination of electrolytes. The throughput per hour is 800 tests for clinical chemistry (1200 with electrolytes). The system consists of the analyzer which performs all functions required for fully automatic sample and test processing. Beginning with the automatic recording of patient samples - provided that they are supplied in barcode-labeled vessels - up to the photometric measurement and results transmission to the computer unit. Additional detailed information about the Hitachi 917 Analyzer is contained in volume II of the premarket notification (K953239) cleared on September 25, 1995.

V. Summary of the technological characteristics of the new device in comparison to those of the predicate.

Tables 3 outlines the technological characteristics (methodologies) of the Abuscreen ONLINE Benzodiazepines test kit in comparison to that of the legally marketed predicate product.

VI. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence:

Tables 3 demonstrates the results of clinical and nonclinical studies performed using the Abuscreen ONLINE Benzodiazepines test kit. The significant performance characteristics relied upon for a determination of substantial equivalence are summarized in this chart. This information concludes that the performance of this device is essentially equivalent to the legally marketed predicate device.

Abuscreen ONLINE Benzodiazepines for Hitachi 917
Table 3

	Proposed: Abuscreen ONLINE Benzodiazepines for Hitachi 917		**Previously Cleared: (K914509)** Abuscreen ONLINE Benzodiazepines (1000 Test Kit)
Methodology	Kinetic interaction of microparticles in a solution as measured by changes in light transmission		Kinetic interaction of microparticles in a solution as measured by changes in light transmission
Sample type	urine		urine
Intended Use	qualitative and semiquantitative detection of benzodiazepines		qualitative detection of benzodiazepines
Calibrator	Abuscreen ONLINE Calibration Pack or Abuscreen ONLINE BENZ 200 Cal Pack or Abuscreen ONLINE BENZ 300 Cal Pack		Abuscreen ONLINE Calibration Pack or Abuscreen ONLINE Calibrator Level 3
Cutoff(s)	100, 200, 300 ng/mL		100 ng/mL
Reagent (active ingredients)	1. Ab reagent: benzodiazepines polyclonal (sheep) antibody in buffer 2. Microparticle reagent: Conjugated benzodiazepine derivative microparticles in buffer 3. Diluent: Buffer		1. Ab reagent: benzodiazepines polyclonal (sheep) antibody in buffer 2. Microparticle reagent: Conjugated benzodiazepine derivative microparticles in buffer 3. Diluent: Buffer
Performance Characteristics:			
Precision Qualitative (100 ng/mL Cutoff):			
	>95% negative at 75 ng/mL >95% positive at 125 ng/mL		>95% negative at 80 ng/mL >95% positive at 120 ng/mL
Within Run	Mean (OD)	CV%	
50 ng/mL	8511	2.4	
75 ng/mL	6728	2.6	
100 ng/mL	5504	2.6	
125 ng/mL	4401	1.6	
150 ng/mL	3641	1.4	
Day-to-Day	Mean (OD)	CV%	
50 ng/mL	8553	2.1	
75 ng/mL	6732	2.3	
100 ng/mL	5510	2.3	
125 ng/mL	4352	1.6	
150 ng/mL	3571	2.4	

Abuscreen ONLINE Benzodiazepines for Hitachi 917
Table 3 (Continued)

	Proposed: Abuscreen ONLINE Benzodiazepines for Hitachi 917		**Previously Cleared: (K914509)** Abuscreen ONLINE Benzodiazepines (1000 Test Kit)	
Precision Qualitative (200 ng/mL Cutoff):				
	>95% negative at 150 ng/mL >95% positive at 250 ng/mL			
Within Run	Mean (OD)	CV%		
100 ng/mL	10430	0.7		
150 ng/mL	8621	1.3		
200 ng/mL	6846	1.6		
250 ng/mL	5311	1.8		
300 ng/mL	4170	1.8		
Day-to-Day	Mean (OD)	CV%		
100 ng/mL	10236	2.7		
150 ng/mL	8482	1.5		
200 ng/mL	6736	1.5		
250 ng/mL	5171	2.6		
300 ng/mL	4015	3.1		
Precision Qualitative (300 ng/mL Cutoff):				
	>95% negative at 225 ng/mL >95% positive at 375 ng/mL			
Within Run	Mean (OD)	CV%		
150 ng/mL	9526	1.7		
225 ng/mL	6998	2.6		
300 ng/mL	5407	1.9		
375 ng/mL	4173	1.3		
450 ng/mL	3305	1.2		
Day-to-Day	Mean (OD)	CV%		
150 ng/mL	9368	2.2		
225 ng/mL	6880	2.7		
300 ng/mL	5218	3.1		
375 ng/mL	4003	2.9		
450 ng/mL	3200	2.4		
Precision Quantitative (100 ng/mL Cutoff):				
Within Run	Mean (ng/mL)	CV%	Mean (ng/mL)	CV%
50 ng/mL	51	2.5	50	6.9
75 ng/mL	80	1.9	81	3.6
100 ng/mL	101	1.0	94	3.1
125 ng/mL	128	1.3	110	2.9
150 ng/mL	149	1.0	151	1.7

Abuscreen ONLINE Benzodiazepines for Hitachi 917
Table 3 (Continued)

	Proposed: Abuscreen ONLINE Benzodiazepines for Hitachi 917		**Previously Cleared: (K914509)** Abuscreen ONLINE Benzodiazepines (1000 Test Kit)	
Precision Quantitative (100 ng/mL Cutoff):				
Day-to-Day	Mean (ng/mL)	CV%	Mean (ng/mL)	CV%
50 ng/mL	50	3.2	53	10.1
75 ng/mL	80	2.1	84	5.0
100 ng/mL	101	1.7	97	4.1
125 ng/mL	129	1.6	112	3.1
150 ng/mL	150	1.5	154	2.7
Precision Quantitative (200 ng/mL Cutoff):				
Within Run	Mean (ng/mL)	CV%		
100 ng/mL	96	4.4		
150 ng/mL	141	2.7		
200 ng/mL	200	1.9		
250 ng/mL	251	1.5		
300 ng/mL	315	1.2		
Day-to-Day	Mean (ng/mL)	CV%		
100 ng/mL	100	5.3		
150 ng/mL	145	3.3		
200 ng/mL	205	2.1		
250 ng/mL	258	2.2		
300 ng/mL	320	2.0		
Precision Quantitative (300 ng/mL Cutoff):				
Within Run	Mean (ng/mL)	CV%		
150 ng/mL	152	2.1		
225 ng/mL	224	1.2		
300 ng/mL	301	1.4		
375 ng/mL	388	1.1		
450 ng/mL	465	0.7		
Day-to-Day	Mean (ng/mL)	CV%		
150 ng/mL	154	2.7		
225 ng/mL	228	1.8		
300 ng/mL	306	2.0		
375 ng/mL	394	1.7		
450 ng/mL	470	4.3		

Accuracy		
100 ng/mL Cutoff	N= 50 Confirmed Pos. 50 Pos. 0 Neg.	N= 48 Confirmed Pos. 47 Pos. 1 Neg.
	N= 10 diluted within 25% above cutoff concentration 10 Pos. 0 Neg.	
	N= 10 diluted within 25% below cutoff concentration 0 Pos. 1 0 Neg.	
200 ng/mL Cutoff	N= 50 Confirmed Pos. 50 Pos. 0 Neg.	
	N= 10 diluted within 25% above cutoff concentration 10 Pos. 0 Neg.	
	N= 10 diluted within 25% below cutoff concentration 0 Pos. 1 0 Neg.	
300 ng/mL Cutoff	N= 50 Confirmed Pos. 50 Pos. 0 Neg.	
	N= 10 diluted within 25% above cutoff concentration 10 Pos. 0 Neg.	
	N= 10 diluted within 25% below cutoff concentration 0 Pos. 1 0 Neg.	
Limit of Detection	100 Cutoff - 13 ng/mL 200 Cutoff - 16 ng/mL 300 Cutoff - 28 ng/mL	61 ng/mL (clinical sensitivity)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 11 1999

Ms. Rita Smith
Senior Regulatory Affairs Associate
Roche Diagnostic Systems, Inc.
Branchburg Township
1080 U.S. Highway 202
Somerville, New Jersey 08876-3771

Re: K983702
Trade Name: Abuscreen ONLINE Benzodiazepine
Regulatory Class: II
Product Code: JXM
Dated: January 18, 1999
Received: January 19, 1999

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983702

Device Name: Abuscreen ONLINE® Benzodiazepines

Indications for Use:

Abuscreen ONLINE Benzodiazepines is an *in vitro* diagnostic test for the qualitative and semiquantitative detection of benzodiazepines in human urine on the Hitachi 917 analyzer at cutoff concentrations of 100 ng/mL, 200 ng/mL, and 300 ng/mL. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Measurements obtained by this device are used in the diagnosis of benzodiazepine use or abuse.

Joan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983702

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)